

AMENDMENTS TO THE DRAWINGS:

The attached replacement drawing sheet includes amendments to FIG. 9. Those amendments include adding the element identified using reference numeral 20, as well as adding arrows in an interior region of the element identified using reference numeral 2. The attached annotated sheet shows the amendments in redline.

Attachments: Replacement Sheet (one (1) sheet including FIG. 9)
 Annotated Sheet showing changes (one (1) sheet including FIG. 9)

REMARKS

In the Final Office Action mailed March 3, 2009, the Examiner took the following actions:

- (a) objected to the drawings under 37 C.F.R § 1.83(b) as allegedly being incomplete;
- (b) objected to the specification as allegedly failing to provide proper antecedent basis for the claimed subject matter;
- (c) rejected claims 26-40, 42-55, 73-85, and 87-110 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement;
- (d) rejected claims 26-40, 42-55, 73-85, and 87-110 under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent No. 5,640,977 to Leahy et al. ("Leahy"); and
- (e) rejected claims 26-40, 42-55, 73-85, and 87-110 under 35 U.S.C. § 102(g), over the sole lost count of Patent Interference No. 104,195.

By this Amendment, claims 26-40, 42-55, 101-105, and 108-110 have been canceled. Accordingly, claims 73-85, 87-100, 106, and 107 are pending in this application. No new matter has been added by this Amendment.

I. **The Examiner Interview**

Initially, Applicant would like to thank the Examiner for conducting the telephone interview with Applicant's representatives, Roland G. McAndrews and Thomas Y. Ho, on February 2, 2009. The Interview Summary mailed March 3, 2009 accurately reflects the issues discussed, and the agreements made, during the interview. The discussion that follows is consistent with comments made during the interview.

II. The Objection to the Drawings Should be Withdrawn

On page 8 of the Office Action, the drawings were objected to under 37 C.F.R. § 1.83(b) as allegedly being incomplete. According to the Examiner's comments in the Interview Summary, and on pages 2 and 9 of the Office Action, the proposed amended version of FIG. 9 that was presented at the interview remedies the alleged drawing deficiencies, and is supported by the originally-filed application. The attached Replacement Drawing Sheet is based on the proposed amended version of FIG. 9, and thus, it remedies the alleged drawing deficiencies. Accordingly, Applicant requests reconsideration and withdrawal of the drawing objection.

III. The Objection to the Specification Should be Withdrawn

On page 9 of the Office Action, the specification was objected to as allegedly failing to provide proper antecedent basis for the claimed subject matter. In accordance with page 9 of the Office Action, the attached Replacement Drawing Sheet remedies the alleged specification deficiencies associated with the phrases "an entry seal assembly," "controlled pressurized environment inside the surgical device," and "distal ring," recited in the claims. Claims reciting the phrase "primary coupling" have been canceled by this Amendment, rendering the objection to that phrase moot. Accordingly, Applicant requests reconsideration and withdrawal of the objection to the specification.

IV. The Rejection of the Claims Under 35 U.S.C. § 112, First Paragraph Should be Withdrawn

On page 10 of the Office Action, claims 26-40, 42-55, 73-85, and 87-110 were rejected under 35 U.S.C. § 112, first paragraph as allegedly failing to comply with the written description requirement. In particular, the Office Action alleges that claims 105-

110 recite features that do not have support in the originally-filed disclosure. Applicant respectfully requests reconsideration and withdrawal of the claim rejection.

Of claims 26-40, 42-55, 73-85, and 87-110, claims 26-40, 42-55, 101-105, and 108-110 have been canceled by this Amendment. Of the remaining claims (i.e., claims 73-85, 87-100, 106, and 107), claims 106 and 107 are independent. With respect to claim 106, page 10 of the Office Action contends that Applicant's specification does not support the following recitation: "the engagement of the incision engaging portion of the diaphragm with the incision and engagement of the distal ring to the internal body tissue increases with an increase in pressure within the controlled pressurized environment." With respect to claim 107, page 11 of the Office Action contends that Applicant's specification does not support the following recitation: "the engagement of the distal ring to the internal body tissue providing a seal such that the incision engaging portion of the tubular diaphragm is not subject to the controlled pressurized environment, while the internal portion of the tubular diaphragm is subject to the controlled pressurized environment."

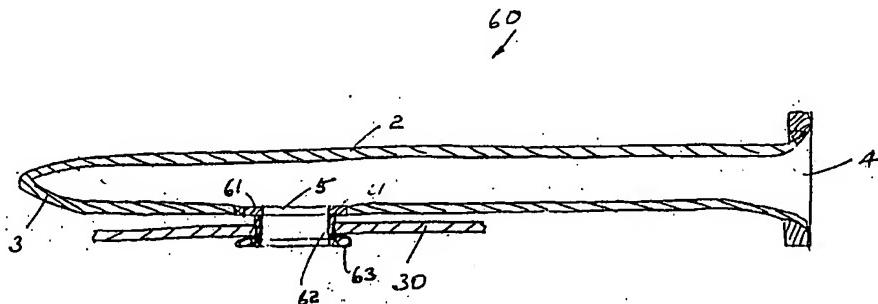
Applicant respectfully disagrees with both of the above contentions. According to the M.P.E.P., "[t]o comply with the written description requirement of 35 U.S.C. 112, para. 1 . . . each claim limitation must be expressly, implicitly, or inherently supported in the originally-filed disclosure." M.P.E.P. § 2163(II)(A)(3)(b). Independent claims 106 and 107 meet the support requirement, and thus, are in compliance with 35 U.S.C. § 112, first paragraph. Claims 106 and 107 will be addressed in turn in the sections below, along with their respective dependent claims.

A. **Claims 73-85 and 106 are Adequately Supported**

The recitation of "the engagement of the incision engaging portion of the diaphragm with the incision and engagement of the distal ring to the internal body tissue increases with an increase in pressure within the controlled pressurized environment" in independent claim 106 would have been considered by a person skilled in the art to be at least implicitly or inherently, if not expressly, supported by the originally-filed application. For example, the paragraph bridging pages 9 and 10 of the originally-filed specification describes a sealing diaphragm in FIG. 9 that includes

a first ring 61 . . . a flexible diaphragm 62 extending from the ring 61 and terminating in an inner ring 63 which is inserted through the incision to engage with the body tissue 30 as illustrated. The sealing diaphragm seals the exit 5 of the sleeve 2 to the incision in the patient's body to create a controlled pressurized environment in the sleeve 2.

(emphasis added). FIG. 9 from the originally-filed application has been reproduced below.



As shown in reproduced FIG. 9, flexible diaphragm 62 extends through the incision. When gas is pumped into the body cavity, the pumped gas flows through flexible diaphragm 62 and fills sleeve 2. With entry 4 of sleeve 2 being sealed by entry sealing means 20, and exit 5 being sealed to the incision, the gas pressure in flexible diaphragm 62 and sleeve 2 will increase, creating the controlled pressurized environment therein.. See Specification, page 8, lines 20-33. It is at least inherent or

implicit that the pumping of the gas into the body cavity, and the increase in gas pressure produced by it, will urge sleeve 2 away and flexible diaphragm 62 relative to body tissue 30 in an upward direction in reproduced FIG. 9 above.

As shown in reproduced FIG. 9, however, inner ring 63 will engage body tissue 30, keeping flexible diaphragm 62 from sliding out of the incision. As more gas is pumped into the body cavity, and gas pressure therein increases, sleeve 2 and flexible diaphragm 62 will be increasingly urged upward. Under such conditions, it is at least implicit or inherent that the force created between inner ring 63 and body tissue 30 by the urging will increase as ring 63 holds flexible diaphragm 62 and sleeve 2 in place.

As inner ring 63 keeps sleeve 2 and flexible diaphragm 62 in place, in the face of increasing gas pressure in the body cavity and the resultant urging it produces, it is at least implicit or inherent that the increased gas pressure will tend to expand the interior volume of sleeve 2 and flexible diaphragm 62. Since flexible diaphragm 62 is held at partially in contact with body tissue 30, its expansion will increase its engagement with the incision.

For at least the above reasons, a person skilled in the art would have considered the recited features in independent claim 106 to be supported, at least implicitly or inherently, if not expressly, by the originally-filed application. Accordingly, since Applicant's specification provides adequate support for the features recited in claim 106, the rejection of claims 73-85 and 106 under 35 U.S.C. § 112, first paragraph is improper and should be withdrawn.

B. Claims 87-100 and 107 are Adequately Supported

The recitation of “the engagement of the distal ring to the internal body tissue providing a seal such that the incision engaging portion of the tubular diaphragm is not subject to the controlled pressurized environment, while the internal portion of the tubular diaphragm is subject to the controlled pressurized environment” in independent claim 107 would have been considered by a person skilled in the art to be at least implicitly or inherently, if not expressly, supported by the originally-filed application.

For example, the paragraph bridging pages 9 and 10 of the originally-filed specification describes a sealing diaphragm that includes

a first ring 61 . . . a flexible diaphragm 62 extending from the ring 61 and terminating in an inner ring 63 which is inserted through the incision to engage with the body tissue 30 as illustrated. The sealing diaphragm seals the exit 5 of the sleeve 2 to the incision in the patient's body to create a controlled pressurized environment in the sleeve 2.

(emphasis added). In order to seal exit 5 to the incision, and create the controlled pressurized environment in sleeve 2, it is at least implicit or inherent that a flow path exists between the body cavity, exit 5, and the interior of sleeve 2, where the controlled pressurized environment is created. Thus, in FIG. 9, at least the following surfaces must form a leakproof boundary to create the flow path: the interior surface of body tissue 30, a portion of the surface of inner ring 63, the interior surface of tubular diaphragm 62, and the interior surface of sleeve 2. Only those surfaces forming the leakproof boundary are subjected to the controlled pressurized environment. Other surfaces, such as the exterior surface of body tissue 30, the exterior (i.e., incision engaging) surface of tubular diaphragm 62, and the exterior surface of sleeve 2 are not subjected to the controlled pressurized environment, since that would require providing

a leakage path in the leakproof boundary that would prevent the controlled pressurized environment in sleeve 2 from being created. Moreover, subjecting the aforementioned exterior surfaces to the controlled pressurized environment would require unsealing exit 5 from the incision, directly contradicting the express requirements set forth in the above-quoted passage from pages 9 and 10 of Applicant's specification.

For at least the above reasons, a person skilled in the art would have considered the recited features in independent claim 107 to be supported, at least implicitly or inherently, if not expressly, by the originally-filed application.

Accordingly, since Applicant's specification provides adequate support for the features recited in independent claim 107, the rejection of claims 87-100 and 107 under 35 U.S.C. § 112, first paragraph is improper and should be withdrawn.

V. The Rejection of the Claims Under 35 U.S.C. § 102(e) and 102(g) Should be Withdrawn

On pages 12 and 16 of the Office Action, claims 26-40, 42-55, 73-85, and 87-110 were rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by Leahy, and under 35 U.S.C. § 102(g) over the sole lost count of Patent Interference No. 104,195. Applicant respectfully requests reconsideration and withdrawal of the claim rejections at least for the reasons outlined below.

Any estoppel issues raised in the Office Action would be rendered moot upon a showing of the non-obviousness of the pending claims over Leahy. See Interview Summary mailed April 29, 2008. Thus, because the non-obviousness of the pending claim set is the linchpin to overcoming both the prior art rejection under 35 U.S.C. § 102(e), and the estoppel-based rejection under 35 U.S.C. § 102(g), the following remarks begin with a discussion of non-obviousness.

A. The Leahy Reference

Leahy discloses a surgical apparatus 10 for permitting hand-assisted laparoscopic surgery. Referring to FIGS. 3 and 4 of Leahy, the apparatus 10 includes an outer sleeve 18 having an axial entry opening 23a and a lateral exit opening 24, exit opening 24 being located adjacent an incision in a patient. A first sealing means is provided for sealing the exit opening 24, and a second sealing means is provided for sealing the entry opening 23a, creating a sealed chamber C in sleeve 18 that prevents gas from escaping from an insufflated abdominal cavity A. See Leahy, column 3, lines 29-33. The first sealing means includes an adhesive 28 on a lower exposed flange 26 of the apparatus, the adhesive being adhered directly to the patient's body or to the body by way of a drape D that is adhered to the body. See Leahy, column 3, lines 60-67; column 5, lines 14, 15, and 31-34; and column 7, lines 36-43. The second sealing means may include, for example, an inflatable cuff 20 located at the entry opening 23a. See Id. at column 3, lines 49-54. In addition, Leahy discloses a wound protector 12 separate from the surgical apparatus 10 comprising a thin flexible tube 13 for engaging a wound W in an abdominal wall L of the patient, and flexible O-rings 14 and 16 located at opposite ends of tube 13. See Id. at column 2, lines 9 and 10; and column 4, lines 1-10.

B. Independent Claim 106 is Not Anticipated by Leahy

Independent claim 106 recites, *inter alia*,

an entry seal assembly located proximal the tubular diaphragm, the entry seal assembly configured to maintain a pressurized environment inside the surgical device such that the engagement of the incision engaging portion of the diaphragm with the incision and engagement of the distal ring to the internal body tissue increases with an increase in pressure within the controlled pressurized environment.

Leahy does not teach that increasing the pressure in chamber C will increase engagement of distal ring 14 and tube 13 with abdominal wall L and wound W. This is due to the coupling of surgical apparatus 10 of Leahy to the top of abdominal wall L using flange 26 and adhesive 28. As long as flange 26 is adhered to the top of abdominal wall L, increasing pressure in chamber C will not urge tube 13 and ring 14 relative to wound W and abdominal wall L to increase their engagement with wound W and abdominal wall L. Thus, adhesive couplings, like those in Leahy, fail to utilize the insufflation pressure to assist in coupling the device to the patient. Rather, such adhesive couplings work against the insufflation pressure by tending to separate or detach at increased pressures.

The increase in engagement with increasing pressure, described in independent claim 106, provides numerous advantages that are not disclosed or recognized in Leahy. For example, in the present application, increasing the engagement of tubular diaphragm 62 and distal ring 63 with the incision and body tissue 30 using an increase in pressure allows coupling of surgical device 60 to the patient without requiring the use of adhesive. In contrast, a device that relies on adhesive coupling, such as surgical apparatus 10 of Leahy, to secure the device to a patient outside the body would not necessarily stretch or tension the material extending out from inside the body, and thus would require appropriate sizing to match the thickness of the patient's skin to assure that a distal end of the material does not dangle within the patient's body. Accordingly, devices that utilize adhesives to couple the device to a patient outside the body would need to be separately sized for the many different skin thicknesses of patients to avoid excess material from extending into the body. This drawback is present in Leahy. See

Leahy, column 4, lines 48-59. For at least the above reasons, new independent claim 106 is novel and non-obvious over Leahy.

C. Independent Claim 107 is Not Anticipated by Leahy

Independent claim 107 recites, *inter alia*,

the engagement of the distal ring to the internal body tissue providing a seal such that the incision engaging portion of the tubular diaphragm is not subject to the controlled pressurized environment, while the internal portion of the tubular diaphragm is subject to the controlled pressurized environment.

Leahy discloses that flange 26 and adhesive 28 form the first sealing means.

See Leahy, column 3, lines 60-67. This suggests that flange 26 of Leahy acts as a boundary structure having a first side (below flange 26 in FIG. 3) subject to the same pressure as the pressurized gas in cavity A, and a second side (above flange 26 and outside of sleeve 18 in FIG. 3) subject to atmospheric pressure. Since both the wound engaging portion of tube 13 and the internal portion of tube 13 are on the first side of the boundary (below flange 26 in FIG. 3), they are both subject to the pressure associated with the pressurized gas in cavity A.

Applicant's claimed arrangement of having the internal portion of tubular diaphragm 62 subject to the controlled pressurized environment, while having the wound engaging portion of tubular diaphragm 62 not subject to the controlled pressurized environment, provides numerous advantages that are not disclosed or recognized in Leahy. The arrangement allows distal ring 63 and diaphragm 62 to together form the only coupling with the patient's body. As such, the use of an adhesive to maintain coupling to the patient is entirely avoided, along with the drawbacks associated with using adhesive (discussed above with respect to independent claim

106). Additionally, the arrangement provides advantages in terms of coupling and ability to adapt to different skin thicknesses (also discussed above with respect to claim 106). For at least the above reasons, independent claim 107 is novel and non-obvious over Leahy.

Since independent claims 106 and 107 are novel and non-obvious over Leahy, and because the showing of non-obviousness serves to overcome both the prior art rejection under 35 U.S.C. § 102(e), as well as the estoppel-based rejection under 35 U.S.C. § 102(g) (see the Interview Summary mailed April 29, 2008), Applicant submits that independent claims 106 and 107 are allowable. In addition, Applicant hereby incorporates the arguments for patentability presented in the Reply to Office Action dated May 5, 2008 in support of the allowability of the pending claims.

D. The Dependent Claims are Not Anticipated by Leahy

Applicant submits that the claims depending either directly or indirectly from independent claims 106 and 107 are novel, non-obvious, and allowable for at least the same reasons that claims 106 and 107 are novel, non-obvious, and allowable. In addition, the dependent claims recite unique combinations that are neither taught nor suggested by the cited art, and therefore are also separately patentable.

E. The Pending Claims Are Not Anticipated By the Patented Claims in Leahy

On page 12 of the Office Action, claims 26-40, 42-55, 73-85, and 87-110 were rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by Leahy. In particular, on page 14 of the Office Action, the following is asserted:

the scope of the patented claims of Leahy are so broad they also cover a surgical device and method of providing sealed access through an incision without the use of an adhesive Therefore, the patented claims of

Leahy read upon Figure 9 of the present application and anticipate the [claims] of the present application.

(emphasis in original). Page 14 also asserts that

[f]urthermore, during the interference, applicant admitted in Appendix A of the Amendment filed on January 5, 1997 that claim 28 of the Leahy patent reads upon Fig. 9 In order to invoke the interference, on page 6 of Appendix A, Applicant compared patented claim 28 to Fig. 9 of the present application. Applicant's comparison and analysis of patented claim 28 does not indicate that the adhesive or flange is required when interpreting the scope of this claim. Thus, Applicant acknowledges that the Leahy's device can be used without an adhesive and covers the embodiment of Figure 9 of the present application.

Applicant respectfully traverses the above assertions. Consistent with the scope of the detailed description of Leahy, the claims of Leahy do not disclose or suggest the claimed "engagement of the incision engaging portion of the diaphragm with the incision and engagement of the distal ring to the internal body tissue increases with an increase in pressure within the controlled pressurized environment," of independent claim 106, or the claimed "engagement of the distal ring to the internal body tissue providing a seal such that the incision engaging portion of the tubular diaphragm is not subject to the controlled pressurized environment, while the internal portion of the tubular diaphragm is subject to the controlled pressurized environment," of independent claim 107.

Accordingly, the claims of Leahy cannot anticipate either of claims 106 or 107.

In particular, Applicant respectfully disagrees with the statements in the Office Action that the claims of Leahy "are so broad they also cover a surgical device and method of providing sealed access through an incision without the use of an adhesive" (emphasis in original) and "[t]herefore, the patented claims of Leahy read upon Figure 9 of the present application and anticipate the [claims] of the present

application." Office Action, page 14. The breadth of the claims of Leahy are not relevant to the issue of whether they anticipate the claims of the present application.

The appropriate test for anticipation is whether the claims of Leahy expressly or inherently include every element of the rejected claims of this application. This type of analysis arises frequently in the context of double patenting rejections where claims of one patent application (or issued patent) are used to reject claims of another patent application. M.P.E.P. § 804 supports the distinction between breadth (or dominance) of claims and anticipation by stating:

Domination and double patenting should not be confused. They are two separate issues. One patent or application "dominates" a second patent or application when the first patent or application has a broad or generic claim which fully encompasses or reads on an invention defined in a narrower or more specific claim in another patent or application. Domination by itself, i.e., in the absence of statutory or nonstatutory double patenting grounds, cannot support a double patenting rejection.

(emphasis added).

Accordingly, whether or not the claims of Leahy "read upon" or dominate Fig. 9 of the present application, or are in some aspects broader than the claims of the present application, is irrelevant to the anticipation analysis.

Similarly, the comments in the Office Action alleging that statements in the relevant interference proceeding amount to an acknowledgement by the Applicant that the Leahy device "covers the embodiment of Figure 9 of the present application" are also irrelevant to the anticipation analysis. Office Action, page 14. Along these same lines, Applicant disagrees with the comments in the Office Action alleging that certain statements in the relevant interference proceeding concerning the scope of the claims of Leahy are an acknowledgement that "the claims of Leahy's device can be used

without an adhesive." Office Action, page 14. Even assuming the statements made during the relevant interference proceeding were to amount to an admission that the scope of certain claims of Leahy were broad enough to cover the device depicted in Fig. 9 of the present application, such statements would in no way imply that the claims disclose the features claimed in independent claims 106 and 107 of this application.

In view of the above, Applicant submits that independent claims 106 and 107 are not anticipated by either the claims or detailed description of the Leahy patent. Accordingly, Applicant requests reconsideration and withdrawal of the claim rejection. Additionally, the rejection of claims 73-85 and 87-100 that depend from claims 106 and 107 should be withdrawn for at least the reasons provided above.

VII. Benefit Under 35 U.S.C. § 119(d)

On page 5 of the Office Action, it is asserted that Applicant is not entitled to the priority date of at least Irish Patent Application No. 930649 ("the '649 application"), filed September 6, 1993, under 35 U.S.C. § 119(d). Applicant respectfully disagrees.

Applicant's claims are entitled to the priority date of at least the '649 application for at least the reasons discussed in the Reply to Office Action filed January 5, 2006, and the Reply to Office Action filed May 5, 2008. Further, contrary to page 4 of the Office Action, the Board of Patent Appeals and Interferences ("BPAI") has not held that as a matter of law, Applicant is not entitled to the priority date of the '649 application. First, to the extent that the withholding of the priority date is based on estoppel, Applicant's showing of non-obviousness over Leahy renders that basis moot (per the Interview Summary, and paragraph bridging pages 5 and 6 of the Office Action). Second, case law, particularly, In re Deckler, 977 F.2d 1449 (Fed. Cir. 1992), does not

support the withholding of the priority date of the '649 application from Applicant. The sole issue in Deckler was whether the losing party in an interference proceeding is entitled to a patent covering claims the party admits are patentably indistinguishable from the claim involved in the interference. See Id. at 1450. Applicant, however, is seeking claims that are patentably distinguishable from the claim involved in the interference. Thus, Deckler is inapplicable to the present case. Moreover, Deckler deals with preclusion as to claims, and is silent as to preclusion as to priority under 35 U.S.C. § 119(d). Third, for at least the reasons provided on pages 21-23 of the Reply to Office Action filed January 5, 2006, the inventorship inconsistency between the '649 application and the present application has been satisfactorily explained. As such, the "inconsistency of disagreement has been resolved." See Office Action, page 5. Thus, Applicant respectfully submits that Applicant is entitled to the benefit of the priority date of at least the '649 application, and that Leahy is not prior art under 35 U.S.C. § 102(e): Leahy was filed on September 2, 1994, while the present invention should be accorded the benefit of the September 6, 1993, priority filing date of the '649 application.

On page 5 of the Office Action, the Examiner indicated that without a copy of the decision in Curtis Mfg. Co., Inc. v. Plasti-Clip Corp., 933 F. Supp. 94 (D.N.H. 1995) ("Curtis"), the Examiner would be unable to make a determination on Applicant's position with respect to that case. Thus, a copy of the Curtis decision is attached (see Exhibit A). Applicant's position is that the BPAI's denial of Applicant's right to the priority date under 35 U.S.C. § 119(d) came in the form of a decision on a preliminary motion. A decision on a preliminary motion in an interference proceeding is not a final

judgment for res judicata or estoppel purposes. See Curtis at 103. For this additional reason, Applicant is not barred from seeking benefit of the priority date of the '649 application, and is entitled to the priority date for at least the reasons discussed in the Reply to Office Action mailed January 5, 2006, and the Reply to Office Action mailed May 5, 2008.

CONCLUSION

Should the Examiner believe that a discussion of this application would expedite resolution of outstanding matters, the Examiner is invited to call the undersigned at (202) 408-4420.

The Office Action contains characterizations of the claims and the related art with which Applicant does not necessarily agree. Unless expressly noted otherwise, Applicant declines to subscribe to any statement or characterization in the Office Action. Further, in discussing the specification, claims, and drawings in this Reply, it is to be understood that Applicant is in no way intending to limit the scope of the claims to an exemplary embodiment described in the specification or abstract and/or shown in the drawings. Rather, Applicant is entitled to have the claims interpreted broadly, to the maximum extent permitted by statute, regulation, and applicable case law.

In view of the foregoing amendments and remarks, Applicant respectfully requests reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge
any additional required fees to our Deposit Account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.



Dated: August 21, 2009

By: _____

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Attachments: **Replacement Drawing Sheet (one (1) page, FIG. 9)**
Annotated Drawing Sheet (one (1) page, FIG. 9)

ANNOTATED SHEET

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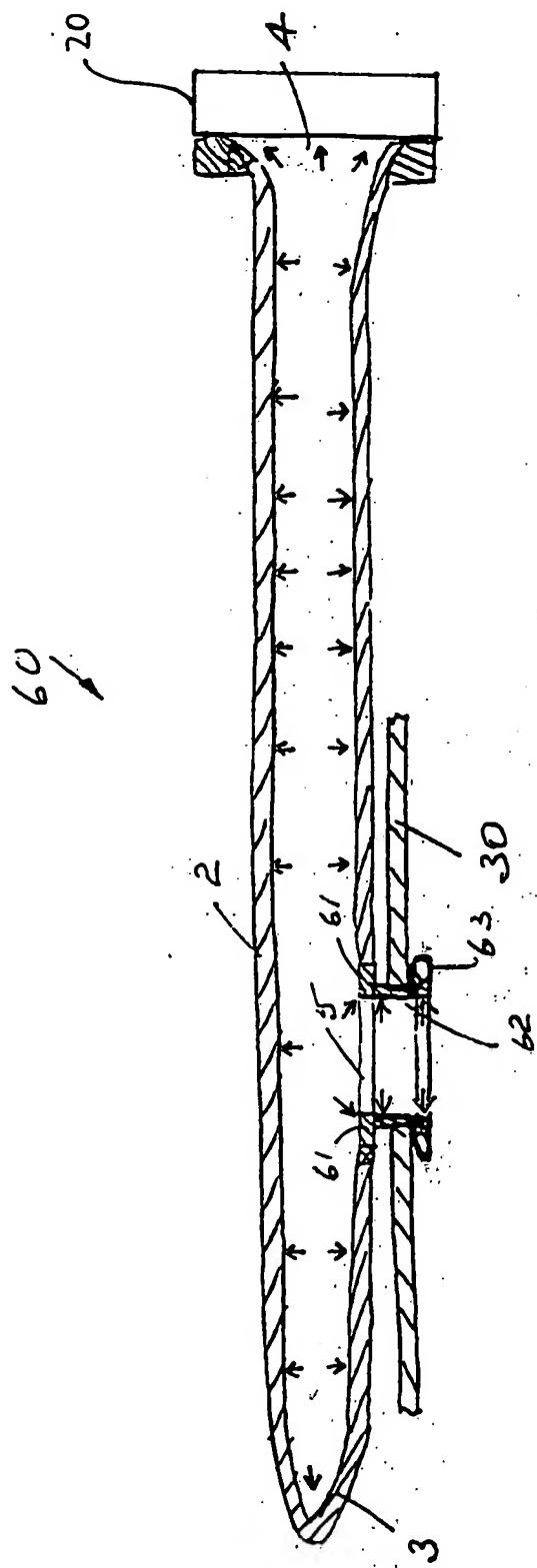


Fig. 9